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K122860

510(k) Summary
Section 21 CFR 807.92

NOV 14 2012

Submitter: KLS Martin, L.P.
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Contact Person: Jennifer Damato
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Date Prepared: November 1, 2012

Trade Name: Recon Talon

Common Name: Bone Fixation Appliance

Classification: Bone Fixation Plate
Class II, 21 CFR 888.3030, Product Code HRS

Predicate Devices: KLS Martin Sternal Talon **(K051165, K070169)**
Synthes Sternal Fixation System – Modification to Surgical Technique **(K093772)**

Device Description:
The KLS Martin Recon Talon is a two-piece clamping device, which has on either end an attached plate. Plate thickness ranges from 1.0 mm to 3.0 mm and screw diameter ranges from 2.3 mm to 3.2 mm. The two-piece clamping device utilizes a ratcheted locking system. Each piece of the device is affixed to opposing sides of the sternum and interlocks to provide stabilized fixation. The device has a three position screw, allowing the ratchet to open, close, and lock. In an emergency situation the device can be reopened by turning the screw to the open position. Secondary emergency re-entry is provided by cut points adjacent to the screw.

Indications for Use:
The KLS Martin Recon Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

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Technological Characteristics:

Characteristic	Recon Talon	Sternal Talon (K051165 & K070169)	Synthes Sternal Fixation System (K093772)
Material	TI-6AL-4V	TI-6AL-4V or CP Titanium	Titanium (grade unknown)
Plate Thickness	1.0 - 3.0 mm	N/A	2.4 mm
Screw Diameter	2.3 - 3.2 mm	N/A	3.0 mm
Sterility	Provided sterile	Provided sterile & non-sterile	Provided non-sterile
Method of Closure	Orthopedic fixation using a positive locking system incorporating titanium plates and screws	Orthopedic fixation using a positive locking system	Orthopedic fixation using a titanium plate and screw system

Similarities to Predicates
The Recon Talon utilizes the same ratcheted locking system as the Sternal Talon (K051165, K070169) and incorporates rib-to-rib fixation plates affixed with titanium screws similar to those included in the Synthes Sternal Fixation System (K093772). Placement and fixation of the Recon Talon is similar to the method used for the Synthes Sternal Fixation System (K093772).

Differences to Predicates
The Recon Talon design incorporates characteristics from the KLS Martin Sternal Talon (K01165, K070169) and the Synthes Sternal Fixation System (K093772).

Performance Testing:
Three different modes were evaluated in separate performance tests. Fatigue testing was performed on individual Recon Talons using 75 N for 5 million cycles with no device failures. Tensile tests were also performed on individual Recon Talons to failure where the maximum load was 1.06 kN. System testing was conducted using Sawbones in 3 loading modes: transverse, longitudinal and lateral shear. The results were 0.92, 1.23, and 1.65 kN respectively. Method of failure in all system testing was either pullout at the screw/Sawbone interface or Sawbone failure. No device failures were noted in system testing. Results met the defined test conditions and demonstrate safety and effectiveness. Packaging and sterilization validation to ISO 11607-1, -2 and ISO 11137-1, -2 demonstrate conformance to the standards tested.

Conclusion:
Performance testing results demonstrate that the Recon Talon is substantially equivalent to the KLS Martin Sternal Talon (K051165, K070169). In addition, similarities in the technological characteristics support substantial equivalence to the KLS Martin Sternal Talon (K051165, K070169) and the Synthes Sternal Fixation System (K093772).

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

KLS Martin L.P.
% Ms. Jennifer Damato
Director of Quality Management and Regulatory Affairs
11201 Saint Johns Industrial Parkway South
Jacksonville, Florida 32246

Letter Dated: November 14, 2012

Re: K122860
Trade/Device Name: Recon Talon
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: Sept. 11, 2012
Received: Sept. 18, 2012

Dear Ms. Damato:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Laurence D. Coyne

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

SECTION 4

510(k) Number (if known): K122860

Device Name: Recon Talon

Indications for Use:

The KLS Martin Recon Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122860